IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	10/643,261
Applicant:	Ilya Yampolsky et al.
Filed:	August 20, 2003
Title:	STENT WITH IMPROVED RESISTANCE TO MIGRATION
T.C./A.U.:	3731
Examiner:	Kevin Truong
Confirmation No.:	4665
Notice of Appeal Filed:	November 26, 2008
Docket No.:	BSI-540US

AMENDED APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated June 26, 2008, and the Advisory Action dated November 14, 2008, of claims 1-12.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. This Amended Brief is being filed within the time allowed for response to the Notification of Non-Compliant Appeal Brief mailed on May 5, 2009.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, were provided with the filing of the original Appeal Brief on April 13, 2009.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Boston Scientific Scimed, Inc. by virtue of an assignment by the inventors to Scimed Life Systems, Inc. recorded on October 29, 2004, at Reel/Frame 014088/0922 and a subsequent assignment by Scimed Life Systems, Inc. to Boston Scientific Scimed, Inc. by virtue of an assignment recorded on November 6, 2006, at Reel/Frame 018505/0868. Boston Scientific Scimed, Inc. is a subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to the subject matter of this Appeal.

III. STATUS OF CLAIMS

Claims 1-12 are pending, with claims 1-12 being the subject of the present appeal. Claims 13-17 have been canceled.

IV. STATUS OF AMENDMENTS

The amendment filed on September 22, 2008, which canceled withdrawn claims 13-17, has been entered. No amendments have been filed subsequent to the September 22, 2008 amendment. Claims 1-12 were not amended and are presently pending.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

As set forth in the pending independent apparatus claim 1, the presently claimed invention relates to a bifurcated stent that is expandable from an unexpanded state to an expanded state. The stent comprises a trunk region. The trunk region has a self-expandable section constructed from a first material and a balloon expandable section constructed from a second material. The balloon expandable section extends from a first end of the self-expandable section. In the expanded state the balloon expandable section is less compressible than the self-expandable section. At least one self-expandable branch is fixedly connected to and extends from a second end of the self-expandable section of the trunk region. In the expanded state the balloon expandable section is less compressible than the at least one self-expandable branch. The self-expandable branch does not include a balloon-expandable section.

As explained in the specification, beginning on page 5, line 15, an exemplary embodiment of the presently claimed invention relates to a bifurcated stent that is expandable from an unexpanded state to an expanded state. The stent comprises a trunk region. As further explained in the specification, beginning on page 5, line 19, the trunk region has a self-expandable section constructed from a first material (page 6, line 27) and a balloon expandable section page 5, line 23) constructed from a second material (page 6, line 29). As further explained in the specification, beginning on page 5, line 12, and in FIG. 1, the balloon expandable section extends from a first end of the self-expandable section. As further explained in the specification, beginning on page 5, line 24, in the expanded state the balloon expandable section is less compressible than the self-expandable section. As further explained in the specification, beginning on page 5, line 15, and in FIG. 1, at least one self-expandable branch is fixedly connected to and extends from a second end of the self-expandable section of the trunk region. As further explained in the specification, beginning on page 5, line 24, in the expanded state the balloon expandable section is less compressible than the at least one self-expandable branch. As further explained in the specification, beginning on page 6, line 25, the self-expandable branch does not include a balloon-expandable section.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-12 are patentable under 35 U.S.C. 103 over U.S. Patent No. 7,131,991 to Zarins et al. in view of U.S. Patent No. 5,383,892 to Cardon et al.

VII. ARGUMENT

A. Claims 1-12 are patentable under 35 U.S.C. 103 over U.S. Patent No. 7,131,991 to Zarins et al. in view of U.S. Patent No. 5,383,892 to Cardon et al.

Claims 1-12 stand rejected under 35 U.S.C. 103 as unpatentable over U.S. Patent No. 7,131,991 to Zarins et al. ("Zarins") in view of U.S. Patent No. 5,383,892 to Cardon et al. ("Cardon").

Of the rejected claims, claim 1 is independent. Claim 1 recites, *inter alia*, a bifurcated stent being expandable from an unexpanded state to an expanded state. The stent comprises a trunk region having a self-expandable section constructed from a first material and a balloon expandable section constructed from a second material. The balloon expandable section extends from a first end of the self-expandable section. In the expanded state the balloon expandable section is less compressible than the self-expandable section. The stent also includes at least one self-expandable branch fixedly connected to and extending from a second end of the self-expandable section of the trunk region. In the expanded state the balloon expandable section is less compressible than the at least one self-expandable branch. *The self-expandable branch does not include a balloon-expandable section.*

An exemplary embodiment of the stent of the present invention includes a trunk having a mechanically or balloon-expandable proximal section that is adapted to firmly engage that part of the body lumen surrounding the proximal section. Specification, page 5, lines 21-22. The mechanical or balloon-expandable proximal section has greater rigidity, which prevents the stent from working its way from its originally deployed position. Specification, page 6, lines 18-24. The stent further includes the trunk having a distal section and branches that share a common compressibility that is adapted to permit the distal section and the branches to conform to the shape of the body lumens surrounding them at their deployment site and to be easily advanced through the tortuous confines of the body lumens. *Id*, page 5, lines 15-19.

The Office Action dated June 26, 2008 alleges that Cardon teaches that the end portion of a hybrid stent device should be balloon expandable in order to obtain the advantage of insuring that the device is anchored in the blood vessel. Office Action, page 2, para 2. Applicants respectfully submit that a complete reading of Cardon indicates that the combination according to Cardon's invention of flexible

parts and rigid parts in the structure of the stent, is not any kind of combination, but that the stent according to Cardon's invention "consists of the alternate juxtaposition of axially rigid cylindrical parts and at least one axially flexible cylindrical part; said stent comprising *axially rigid parts at its two ends*." Cardon, col. 1, lines 35-43, emphasis added.

Further, Cardon teaches an alternate juxtaposition of axially rigid and axially flexible parts such that:

"there are *always*:

one axially rigid part at *each end* of the stent;

two axially rigid parts on either side of an axially flexible part."

Cardon, Col. 1, lines 49-51 (emphasis added).

Cardon also provides exemplary embodiments of his invention, where "the structures of the stents follow the sequences indicated hereinbelow:

1) rigid end part-flexible part-rigid end part

R-F-R

2) rigid end part-flexible part-intermediate part-flexible part-rigid end part

R-F-R'-F-R"

Cardon, Col. 1, line 65 - Col. 2, line 6.

Again, Cardon recites that "the stents according to the invention *always* have rigid ends." Cardon, Col. 2, lines 54-55 (emphasis added). Such an arrangement is said by Cardon to enable stents to fasten securely to the walls of the parts of the human body in which they are implanted and minimizes the risk of disturbances in the flow of fluids circulating in the parts of the human body. Cardon, Col. 1, lines 53-57. Therefore, instead of disclosing a self-expandable branch that is more compressible than a balloon expandable section, Cardon teaches relatively rigid ends at both ends.

Still further, Cardon teaches that the axially flexible cylindrical parts are always inserted, in the structure of the stents according to Cardon's invention, between two axially rigid cylindrical parts. Cardon, Col. 4, lines 12-15. Therefore, Cardon *must* always include an axially rigid part at each end of his device.

Both the flexible and rigid parts of Cardon's stents are radially expandable under the action of an expandable balloon. Cardon, Col. 4, lines 44-48. Therefore, the stent disclosed by Cardon *requires* the rigid end portion to be balloon-expandable.

In attempting to combine the teaching of Cardon with the teaching of Zarins to arrive at the claimed invention, the Office Action ignores the requirement in Cardon that *both* ends of the stent be rigid and balloon-expandable. As stated in M.P.E.P. §2141.02 VI, however, "[a] prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 202 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)."

In *Bausch & Lomb v. Barnes-Hind/Hydrocurve*, 230 USPQ 416 (CAFC 1986), the defendant selected a single line from a prior art reference to support its assertion that the process disclosed in the reference was exactly the same as the process claimed in the patent-in-suit. The court, however, held that the statement relied upon by the defendant was taken out of context and stated that a full appreciation of the statement required consideration of the immediately following sentences in the same paragraph and the paragraph after that. *Id*. Similarly, in the present case, while the Office Action alleges that Cardon teaches that the end portion of a hybrid stent device should be balloon expandable, the Office Action must also take into consideration the total teaching of Cardon, which clearly teaches that there is always one axially rigid part at *each end* of the stent.

Because, in accordance with M.P.E.P. §2141.02 VI, Cardon must be considered in its entirety, a person of ordinary skill in the art, having Cardon in front of him and seeking to modify Zarins with the teaching of Cardon, would understand that such modification requires *both* ends of Zarins to be axially rigid. The result of this modification, if it could be made at all, would result in a bifurcated stent having a branch with a relatively rigid end, as opposed to the claimed invention, which recites that the self-expandable branch does not include a balloon-expandable section.

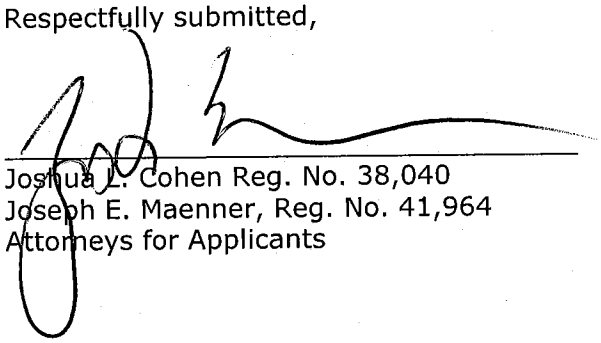
Further, "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238 at 241, 147 USPQ 391 at 393 (CCPA 1965). As discussed above, Cardon clearly states the stents according to his invention *always* have relatively rigid ends. This statement clearly suggests to one of ordinary skill in the art that if one is to look to Cardon to modify Zarins by incorporating a rigid end at one end of the Zarins stent,

one cannot ignore the requirement that *both* of the ends be rigid, and must therefore also incorporate a rigid end at the other end of the Zarins stent. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994). By *requiring* one relatively rigid part *at each end* of the stent, Cardon expressly teaches away from claim 1, which precludes a balloon expandable (relatively rigid) section anywhere in the branch, let alone at the end of the branch.

Because Cardon, when taken as a whole, teaches away from a balloon expandable section in the trunk region and a self-expandable branch extending from a self-expandable section of the trunk region, *wherein the self-expandable branch does not include a balloon-expandable section*, the proposed combination of Zarins with Cardon is improper. Applicants respectfully submit that the rejection of claim 1 is improper and request reconsideration and allowance of claim 1.

Claims 2-12 all ultimately depend from claim 1. Applicants respectfully submit that claims 2-12 are allowable over the proposed combination of Zarins and Cardon for at least the same reasons set forth above with respect to amended claim 1. Applicants respectfully request reconsideration and allowance of claims 2-12.

Respectfully submitted,



Joshua L. Cohen Reg. No. 38,040
Joseph E. Maenner, Reg. No. 41,964
Attorneys for Applicants

Dated: May 15, 2009

P.O. Box 980
Valley Forge, PA 19482-0980
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

CLAIMS APPENDIX

1. (Previously Presented) A bifurcated stent being expandable from an unexpanded state to an expanded state, the stent comprising:

a trunk region, the trunk region having a self-expandable section constructed from a first material and a balloon expandable section constructed from a second material, the balloon expandable section extending from a first end of the self-expandable section, in the expanded state the balloon expandable section is less compressible than the self-expandable section; and

at least one self-expandable branch fixedly connected to and extending from a second end of the self-expandable section of the trunk region, in the expanded state the balloon expandable section is less compressible than the at least one self-expandable branch, wherein the self-expandable branch does not include a balloon-expandable section.

2. (Original) The stent of claim 1 wherein the balloon expandable section of the trunk region comprises a cut tube of stent material comprising a plurality of interconnected members defining a plurality of cell spaces.

3. (Original) The stent of claim 1 wherein the balloon expandable section of the trunk region comprises a cut sheet of stent material formed into a tubular shape, the tubular shape comprised of a plurality of interconnected members defining a plurality of cell spaces.

4. (Original) The stent of claim 1 wherein the self-expandable section of the trunk region and at least a portion of the at least one self-expandable branch is at least partially constructed from at least one strand of braided stent material.

5. (Original) The stent of claim 1 wherein the balloon expandable section of the trunk region comprises at least one distally extending member and the self-expandable section of the trunk region comprises at least one proximally extending member, the at least one proximally extending member and the at least one distally extending member being engaged to each other.

6. (Original) The stent of claim 5 further comprising at least one crimping member, the at least one crimping member disposed about the at least one proximally extending member and the at least one distally extending member.

7. (Original) The stent of claim 6 wherein the at least one crimping member is at least partially constructed of a radiopaque material.

8. (Original) The stent of claim 1 wherein the balloon expandable section of the trunk region is at least partially constructed of stainless steel.

9. (Original) The stent of claim 1 wherein at least one of the self-expandable section of the trunk region and the at least one self-expandable branch is at least partially constructed of a shape memory material

10. (Previously Presented) The stent of claim 1 wherein the shape memory material is nitinol.

11. (Original) The stent of claim 1 further comprising at least one vessel engagement member, the at least one vessel engagement member extending from at least a portion of the balloon expandable section, the at least one vessel engagement member selected from the group consisting of hooks, barbs, T-fasteners, bumps, ridges, and any combination thereof.

12. (Original) The stent of claim 1 further comprising at least one layer of graft material, the at least one layer of graft material positioned on at least one of an inside surface and outside surface of at least a portion of at least one of the trunk region and the at least one self-expandable branch to define a fluid passageway therethrough.

13-17. (Canceled).

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None